

Claims

1. A recombinant fusion protein including a sub-genic Stx2e fragment of the 2e Shiga toxin (Stx2e) in a fusion with a terminal tag the size of which approximately corresponds to the size of the fragment or a fraction of the fragment.
2. The recombinant fusion protein according to claim 1 wherein the sub-genic Stx2e fragment is a B sub-unit (Stx2eB) of the 2e Shiga toxin.
3. The recombinant fusion protein according to claim 1 or 2 wherein the size of the terminal tag is 1 kDa, as a maximum.
4. The recombinant fusion protein according to any one of claims 1 to 3 which has an amino terminal His tag.
5. The recombinant fusion protein according to any one of claims 1 to 4 which has a plurality of crosslinked fusion proteins.
6. A (vaccine) substance composition for various applications in conjunction with the oedematose of animals, particularly those of mammals, specifically pigs, having a sub-genic fragment of the 2e Shiga toxin in a fusion with a terminal tag the size of which approximately corresponds to the size of the fragment or a fraction of the fragment B.
7. The (vaccine) substance composition according to claim 6 wherein the sub-genic Stx2e fragment is a B sub-unit (Stx2eB) of the 2e Shiga toxin.

8. The (vaccine) substance composition according to claim 6 or 7 wherein the size of the terminal tag is 1 kDa, as a maximum.
9. The (vaccine) substance composition according to any one of claims 6 to 8 which has an amino terminal His tag.
10. The (vaccine) substance composition according to any one of claims 6 to 9 which has a plurality of crosslinked fusion proteins.
11. The (vaccine) substance composition according to any one of claims 6 to 10 which comprises one additional antigen or several additional antigens.
12. The (vaccine) substance composition according to claim 11 wherein the one additional antigen or the several additional antigens are selected from the group comprising a *Pasteurella multocida* bacterin including a cell-bonded toxoid, a *Bordetella bronchiseptica* bacterin, an *Erysipelothrix rhusiopathiae* antigen, one or more soluble non-cell toxoids of type D *Pasteurella multocida* and/or *Escherichia coli* and/or *Clostridium perfringens*, disactivated whole cells of type A or D *Pasteurella multocida*, cultures of *Actinobacillus pleuropneumoniae*, *Haemophilus parasuis*, *Escherichia coli*, *Clostridium perfringens*, *Streptococcus suis*, *Mycoplasma hyopneumoniae* as well as Porcine Reproduction and Respiratory Syndrom virus, influenza virus, Pseudorabies virus, and Porcine Circoviruses I and II.
13. The (vaccine) substance composition according to any one of claims 6 to 12 which comprises the 2e Stx-IIe fragment of the 2e Shiga toxin (Stx2e) in a fusion with a terminal tag and/or which comprises at least one additional

antigen each in an immunogenic amount for the vaccination of pigs against the oedematose of the pigs or against the oedematose of the pigs and other viral and/or bacterial infections.

14. (Vaccine) substance compositions according to any one of claims 6 to 13 in compositions and amounts such that if pigs are vaccinated sequentially or simultaneously they immunize them against oedematose of the pigs or against the oedematose of the pigs and other viral and/or bacterial infections.
15. A (vaccine) substance composition having a sub-genic Stx2e fragment of the 2e Shiga toxin (Stx2e) in a fusion with a terminal tag, particularly according to any one of claims 6 to 12, in a W/O/W emulsion, in an O/W emulsion, in a W/O emulsion or in an aqueous suspension.
16. The vaccine) substance composition according to claim 15 including an incomplete Freund adjuvant (iFA).
17. A plasmid containing DNA which encodes a fusion protein according to any one of claims 1 to 6.
18. An E.coli strain transformed by a plasmid according to claim 17.
19. An E.coli strain according to claim 18, deposited with the DSZM – Deutsche Sammlung von Mikroorganismen und Zellkulturen under the number DSM 12721.
20. A method for the recombinant preparation of a sub-genic fragment of the Shiga toxin (Stx2e) in a fusion with a terminal tag wherein a sub-unit from the Stx2e

operon is cloned into a suitable vector system, the resultant recombinant plasmid is transformed into an E. coli strain, the resultant expression system is induced, and the fusion protein is expressed and purified.

21. The method according to claim 20 wherein the sub-genic fragment is a B sub-unit (Stx2eB) of the 2e Shiga toxin.
22. The method according to claim 20 or 21 wherein the size of the terminal tag is 1 kDa, as a maximum.
23. The method according to claim 20 to 22 wherein the terminal tag is an amino terminal His tag.
24. The method according to any one of claims 20 to 23 wherein the expression culture is subjected to a lytic buffer treatment.
25. The method according to any one of claims 20 to 24 wherein the expression culture is subjected to a treatment in a French Press or by means of ultrasonic sound.
26. The method according to any one of claims 20 to 25 wherein the expression culture, after being treated by the French Press or by ultrasonic sound and/or a lytic buffer, is submitted to an affinity chromatographic purification.
27. The method according to claim 26 wherein purification is performed by means of a FPLC.

28. The method according to any one of claims 20 to 27 wherein the purified fusion protein undergoes crosslinking.
29. A method according to any one of claims 20 to 28 wherein the fusion of spleen cells of mice immunized by using the recombinant fusion protein with myelom cells is used for producing hybridoma clones for the preparation of anti-Stx2eB immune globulins.
30. The method according to claim 29 where the antibodies produced by means of the hybridoma clones are employed for the in-process control for the production of the recombinant fusion proteins.
31. The method according to claim 29 or 30 wherein the antibodies produced by the hybridoma clones are used for an affinity chromatographic purification method for the Stx2e holotoxin.